K120262

TORNIER

Implants Chirurgicaux

JUL 25 2012

Summary of Safety and Effectiveness information
Special 510(k) Premarket Notification – HLS Uni Evolution

Date prepared: July 24th, 2012

Regulatory authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1) Device name

Trade name:	**HLS Uni Evolution & U-KneeTec**
Common name:	Unicompartmental Knee Prosthesis
Classification name:	§888.3520, Knee joint femorotibial metal/polymer non-constrained cemented prosthesis

2) Submitter

Tornier
Rue Doyen Gosse
38330 Saint Ismier - France

3) Applicant

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4) Company contact

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5) Classification

Device class:	Class II
Classification panel:	Orthopedic
Product code:	HSX

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S.A.S. au capital de 35 043 008 €
SIRET : 070 501 275 000 13
R.C.S. : 070 501 275
CODE APE : 331 B

SIEGE SOCIAL : rue du Doyen Gosse - 38330 SAINT-ISMIER - FRANCE

6) Equivalent / Predicate device

HLS Uni Evolution, Tornier, K022211

M/G Miller-Galante Unicompartmental Knee System, Zimmer, Inc., K880155 and K942263

7) Device description

The usual goal of a unicompartmental knee prosthesis is to restore the knee joint to its best working condition and to reduce or eliminate pain when only one side of the joint is affected. The HLS Uni Evolution prosthesis is intended to replace the medial or lateral compartment of the femorotibial knee joint. This system is an intermediate solution between osteotomy and total prosthesis.

The HLS Uni Evolution prosthesis consists of a metallic distal femoral resurfacing component and a tibial component. Two kinds of tibial component may be associated to the femoral component: one all polyethylene tibial component and one polyethylene metal-backed tibial component.

The present device modification submission consists in the addition of a new femoral component, named U-KneeTec, to the current cleared range.
This new component is the distal resection version of the HLS Uni Evolution. The U-KneeTec has been designed to be used in association with the already cleared polyethylene tibial component of HLS Uni Evolution.
The U-KneeTec is intended for cemented use only.

8) Materials

The U-KneeTec is manufactured from chromium cobalt alloy according to ISO 5832-4.

9) Indications for use

The HLS Uni Evolution and U-KneeTec unicompartmental knee prostheses are indicated for the replacement of the medial or lateral compartment of the femorotibial knee joint when only one compartment is affected, in order to reduce pain and restore knee function in comparison with preoperative status.
These devices are indicated in the treatment of primary or secondary femorotibial osteoarthritis. The HLS Uni Evolution and U-KneeTec knee prostheses are intended for cemented use only.

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10) Summary of technological characteristics

Main features or system characteristics	U-KneeTec	HLS Uni Evolution	M/G Miller Galante
Materials	CoCr	CoCr	Zimaloy® CoCrMo
Kind of prosthesis	Resecting	Resurfacing	Resecting
Method of fixation	cemented	cemented	cemented
Sizes	5 sizes	5 sizes	7 sizes with, for each, 2 implants: left medial/right lateral or right medial/left lateral
Anchorage	1 peg & 1fin	1 peg & 1 fin	2 pegs
Indications for use	Unicompartmental knee replacement	Unicompartmental knee replacement	Unicompartmental knee replacement
Terminal sterilization	Gamma	Gamma	Gamma
Manufacturer	Tornier	Tornier	Zimmer
K-number	pending	K022211	K880155 and K942263

The indications for use, the technical characteristics (materials, manufacturing principle and method of fixation), the packaging and the sterilization process of the new U-KneeTec implant are similar or identical to the predicate devices.

11) Non-clinical testing

Non-clinical testing was not necessary to determine substantial equivalence between the U-KneeTec and the cited predicate devices.

It has been determined that the proposed new U-KneeTec described in this submission does not induce any new or higher risk compared to the predicate devices.

12) Substantial equivalence conclusion

The U-KneeTec has the same intended use and similar indications, technological characteristics (general features, material, means of fixation, dimensions) as its predicate devices.
The new femoral component U-KneeTec is substantially equivalent to the predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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JUL 25 2012

Re: K120262
Trade/Device Name: HLS Uni Evolution & U-KneeTec
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSX
Dated: July 12, 2012
Received: July 13, 2012

Dear Ms. Bernard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ernest Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120262

Device Name: HLS Uni Evolution & U-KneeTec

Indications For Use:

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These devices are indicated in the treatment of primary or secondary femorotibial osteoarthritis. The HLS Uni Evolution and U-KneeTec knee prostheses are intended for cemented use only.

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120262

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)